



Human Research Protection Program Procedure

SUSPENSIONS AND TERMINATIONS OF IRB-APPROVED RESEARCH

DESCRIPTION

The Institutional Review Board (IRB) has the authority to apply a suspension or termination upon approved human research. The IRB shall promptly notify the Principal Investigator (PI), institutional officials, and regulatory authorities, as appropriate, of the IRB's actions and reasons for the actions.

RESPONSIBILITY

The IRB Chair, Vice-Chair, designee and/or convened IRB may determine when to impose a suspension or terminate a research project.

PROCESS:

Suspension or Termination

The PI, who may be directed by a study sponsor, may suspend or terminate research activities in order to ensure that the rights and welfare of participants remain favorable. The PI will notify the IRB in writing of the decision to suspend or terminate some or all of the research activities including an explanation for the decision. The IRB may request additional information regarding the suspension or termination. The IRB may also initiate quality assurance review for the protocol. The investigator will notify the IRB in writing by submitting a modification prior to lifting the suspension. A new study submission is required for reinitiating a terminated research protocol.

The IRB may also impose a suspension on an approved study by taking action to stop, temporarily or permanently, some or all of the research procedures. The IRB Chair, IRB members, Institutional Official or designee may determine that a suspension must be imposed prior to or during a convened IRB meeting. During a convened meeting, the IRB may review an existing suspension and vote to uphold, alter or overturn the suspension. Consideration will be given to whether or not additional steps are required to protect the rights and welfare of participants during the suspension as well as how and when current participants will be notified of the suspension. Documentation explaining the circumstances in addition to any other actions taken will be included in the IRB record for the study and in the meeting minutes. The IRB Chair, Institutional Official, or designee will communicate this information to the investigator. The investigator may respond to this correspondence and may include further information as well as plans for corrective and preventative actions as applicable. During a

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suspension, the study is not closed and required modifications and continuing review submissions must be submitted in a timely manner.

The IRB Chair, convened IRB, Institutional Official, or designee may take action to terminate an approved study. The IRB Chair, IRB members, Institutional Official, or designee may determine that a suspension must be imposed prior to, or during, a convened IRB meeting. During a convened meeting, the IRB may review an existing suspension and vote to uphold, alter, or overturn the suspension. Consideration will be given to whether or not additional steps are required to protect the rights and welfare of participants during the suspension as well as how and when current participants will be notified of the suspension. Documentation explaining the circumstances in addition to any other actions taken will be placed in the IRB record for the study and in the meeting minutes. The IRB Chair, Institutional Official, or designee will communicate this information to the investigator. The investigator may respond to this correspondence and may include further information as well as plans for corrective and preventative actions as applicable. The IRB Chair or designee will immediately notify the Institutional Official of a decision to terminate or suspend a study. The institutional official will notify the sponsor and governing regulatory authority in writing of all protocols terminated for cause following Human Research Protection Program (HRPP) Policy II.02-*Reporting Unanticipated Problems in Human Research*.

The IRB will ensure that current participants are notified of the termination whenever participants are undergoing interventions or interactions. The IRB will decide whether follow-up of participants for safety reasons is required. If so, the PI will inform current participants of this fact. When the IRB requires follow-up of participants for safety reasons, the investigator must report any adverse events or outcomes to the IRB. Following termination, the study is closed and no additional modification or continuing review submissions are required.

The PI and research staff may be required to receive new or additional training in a certain area to perform future research. If the PI requests to pursue the research, he or she must address all concerns of the IRB and then resubmit the protocol for consideration of approval.

Administrative Closure

A protocol submission under review by the IRB, in which final approval has not yet been granted or released, will be administratively closed six months from the date of submission receipt or pending approval. At the six-month date, the PI will be notified by the HRPP Director or designee regarding the expiration. If the PI provides adequate justification to keep the protocol in the review process, the protocol will be granted a single six-month extension for the PI to obtain IRB approval. Those protocols for which adequate justification has not been received at the six-month date or those protocols that remain in review status at the one-year date will be administratively closed.



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Applicable Regulations, Document(s):

HRPP Policy II.02-*Reporting Unanticipated Problems in Human Research.*

| Adoption Date: | Created by: | Date of Revision: | Revised By: | Summary of Revision: |
|-----------------------|--------------------|--------------------------|--------------------|--|
| 03/05 | AAHRPP committee | | AAHRPP committee | Procedure Title Change, add text relating to social/behavioral IRB |
| | | 06/2014 | A.Braggs-Brown | Revisions to reflect organizational changes |
| | | 09/2014 | A.Braggs-Brown | Revisions reflect AAHRPP recommendations |
| 3/2015 | | 3/2015 | J. Strasser | Revisions for clarification |

Date Adopted March 2015 Signature signed copy on file